REMARKS

Claims 1-21 are currently pending in the instant application. Applicants have amended Claim 9 to address a typographical error. Applicants urge the Examiner to reconsider the maintained rejections for the reasons that follow.

In the Final Office Action, dated January 13, 2003, the Examiner maintained the rejection under 35 U.S.C. 102(b), stating that "Claims 1-2, 4-5, 9-13, [and] 16-20 stand rejected under 35 U.S.C. 102(b) as being anticipated by Cingotti US Patent 5,427,800."

Applicants respectfully disagree with the Examiner because Cingotti does not teach all the limitations of the pending claims. Independent Claim 1, from which Claims 2-10 depend, recites "*a neutral core having a particle size of between 200 and 1600 μm coated with a layer...*", and independent Claim 11, from which Claims 12-21 depend, recites "*coating a neutral core having a particle size of between 200 and 1600 μm with a layer...*" (emphasis added). Cingotti does not disclose "*neutral cores having a particle size of between 200 and 1600 μm coated with a layer*," nor "*coating a neutral core having a particle size of between 200 and 1600 μm with a layer.*"

First, it is important to note that Cingotti distinguishes "granules" from "microgranules." Cingotti discloses *adsorbable microgranules* prepared as follows. First, active ingredients are coated (or deposited) on *granules*, <u>not microgranules</u>. *See, e.g.*, U.S. 5,427,800, col. 1, lines 49-50; col. 2, lines 23-46. Cingotti discloses "*coated granules* of silica or microcrystalline cellulose, *of which the size is on the order of 1 μm.*" *Id.*, col. 3, lines 4-6 (emphasis added). In Example 1, Cingotti discloses *granules* that have "an average primary particle size of eighteen nanometers, (*id.*, col. 3, lines 52-53), and in Example 4,

Cingotti discloses *granules* "having a particle of which size is between 40 and 70 microns," (*id.*, col. 4, lines 60-61). As such, Cingotti does not disclose granules larger than 70 microns.

After coating, the coated granules are then *adsorbed* in the *microgranules*, wherein the *microgranules* contain cavities and ducts into which the *coated granules* can enter. Cingotti states that the "*microgranules* present a multitude of superficial cavities and internal ducts. In practice, these *microgranules* have a dimension between 0.1 and 1 mm....[T]he *coated granules* of silica or microcrystalline cellulose, *of which the size is on the order of 1 μm*, will lodge easily in superficial cavities as well as in the ducts, and remain trapped there." *Id.*, col. 2, lines 67-68, and col. 3, lines 1-8 (emphasis added). In particular embodiments, Cingotti discloses that the *adsorbable microgranules* have "a particle size between 210 and 500 micrometers [or] between 500 and 850 micrometers." *Id.*, col 4., lines 5-7. As such, Cingotti's microgranules may be misnamed *because they are larger than Cingotti's coated granules*. More importantly, *the microgranules are not coated*, and rather, the "coated granules are *adsorbed* in and on the porous microgranules." *Id.*, col. 1, lines 53-53 (emphasis added).

Therefore, Cingotti does not disclose all the limitations of Claim 1 or Claim 11. Cingotti's *granules* are not "neutral cores having a particle size of between 200 and 1600 μm coated with a layer" because they do not have a particle size of between 200 and 1600 μm. Further, Cingotti's *microgranules* are not "neutral cores having a particle size of between 200 and 1600 μm coated with a layer" because they are not coated.

Throughout the specification of U.S. 5,427,800, Cingotti consistently distinguishes the *adsorbing microgranules* from the *coated granules*. *See, e.g., id.*, col. 3, line 30. Further, Cingotti indicates that where the microgranules are directly "impregnanted" without using

adsorbed, coated granules, "a congealed mass is rapidly obtained that is impossible to homogenize, dry and gauge," (*id.*, col. 5, lines 16-17), thereby disclosing an inoperative embodiment. For these reasons, Applicants respectfully assert that Cingotti does not anticipate the subject matter of the claims, and Applicants request that the Examiner reconsider the rejection of the claims under 35 U.S.C. § 102(b).

In the Office Action, the Examiner also maintained the rejection of Claims 3, 6-8, 14-15, and 21 "under 35 U.S.C. § 103(a) as being unpatentable over Cingotti US Patent 5,427,800 and Menzi et al US Patent 6,056,949 in view of Breitenbach et al US Patent 6,120,802." Applicants respectfully disagree with the Examiner for the following reasons.

First, as noted above, Cingotti does not disclose all the limitations of Claim 1 or Claim 11. Further, Cingotti does not contain a "suggestion or motivation to modify the reference" to produce the claimed subject matter. *See* MPEP § 2143.01. On the contrary, the proposed modifications would render the coated granules disclosed in Cingotti "unsatisfactory for [their] intended purpose." *Id.* For instance, Cingotti discloses microgranules no larger than 1 mm as noted above. *See* U.S. 5,427,800, col. 3, line 3. Claim 1 and Claim 11 of the instant application recite a neutral core having a particle size of no less than 200 μm. Clearly, coated granules having a neutral core of no less than 200 μm are not satisfactory for Cingotti's intended purpose, where the microgranules must adsorb the coated granules and the microgranules are no larger than 1 mm. Microgranules of no larger than 1 mm cannot "present a multitude of superficial cavities and internal ducts," (*id.*, col. 2, lines 67-68), in which coated granules of no less than 200 μm "will lodge easily in [the] superficial cavities as well as in the ducts, and remain trapped there," (*id.*, col. 3, lines 6-8).

Further, Cingotti teaches away from directly coating particles of the claimed particle size, where Cingotti states that "direct impregnation of the sorbitol microgranules with the hydroalcoholic solution [results in a] congealed mass...that is impossible to homogenize, dry and gauge." *Id.*, col. 5, lines 16-17. As such, Applicants respectfully contend that Cingotti is an improper reference for a *prima facie* case of unpatentability under 35 U.S.C. § 103(a).

Second, neither Menzi *et al.* nor Breitenbach *et al.* teach "neutral cores" as recited in Claim 1 and Claim 11. In Menzi *et al.*, the flavorant and/or odorant represent active core ingredients, and as such the core is not "neutral." Menzi states that a granulated material is formed "by spraying a flavorant or odorant emulsion *into a core material.*" U.S. 6,056,949, col. 1, lines 60-61 (emphasis added). Further, Menzi describes "flavorant[s]...which can be added *to the core material.*" *Id.*, col. 2, lines 38-39 (emphasis added). As such, Menzi does not teach "neutral cores."

Neither does Breitenbach *et al.* teach "neutral cores." Rather, Breitenbach *et al.* suggests and teaches that the core or inner layers include the "active ingredient." *See* U.S. 6,120,802, col. 3, lines 4-5 ("including the active ingredient in the inner layer(s)"); *id.*, Example 1 ("core containing active ingredients"), Example 2 ("Tablets which contain ibuprofen in the core"), Example 3 ("core with a low release rate" for paracetamol), Example 4 ("hydroxypropylcellulose layer" with "nifedipine as active ingredient...surrounded on both sides..."), Example 5 ("active ingredient dispersed in the PVP core"), Example 6 ("hydroxypropylcellulose core with a low release rate"), Example 7 ("PCP core containing active ingredient"), Example 8 ("core containing active ingredient"), and Example 9 ("core with vitamin A and E"). As such, neither Menzi *et al.* nor Breitenbach *et al.* teach "neutral

cores," and therefore, neither Menzi *et al.* nor Breitenbach *et al.* teach all the limitations of Claim 1 or Claim 11.

For the forgoing reasons, Applicants respectfully contend that the rejection under 35 U.S.C. § 103(a) is improper, and Applicants request that the Examiner reconsider the rejection.

Applicants believe that the present application is now in condition for allowance. Favorable reconsideration of the application is respectfully requested. Applicants representative, M. Scott McBride, looks forward to discussing this application with the Examiner on May 21, 2003, at 11:00 a.m. (EST).

Respectfully submitted,

Date 05/12/03 By _____

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